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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,371	01/06/2000	MING-TANG CHANG	2461-60	9152

7590 07/29/2003

Patricia A. McDaniels, Esq
Senior Attorney/ BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709-3528

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	19

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/477,371	CHANG ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,17,18,21,23,24 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,17,18,21,23,24 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2003 has been entered.

Claims 3-16, 19-20, 22 and 25-27 are cancelled.

Claims 1-2, 21, 23 and 24 are currently amended.

Claims 1-2, 17-18, 21, 23-24 and 28-30 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-2, 17-18, 21, 23-24 and 28-30 are rejected under 35 U.S.C. 112, first

Applicant argues that the rejection is believed to have been obviated by the previous amendment to the specification indicating that the ATCC accession number of the deposited strain EX1965py was deposited under the terms of the Budapest Treaty (reply page 7).

Indicating that the ATCC accession number of the deposited strain EX1965py was deposited under the terms of the Budapest Treaty is not sufficient to overcome the rejection. As indicated at pages 3-4 of the office action mailed February 7, 2002, if the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

Claims 1-2, 17-18, 21, 23-24 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mutant corn seed designated UO95py, does not reasonably provide enablement for other mutant corn seed, or mutant seed of other cereal plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed April 25, 2003, have been fully considered but they are not persuasive.

Applicant argues that the Examiner has failed to state any evidence in support of the opinion that the mutagenesis technique taught in the specification is not a reproducible process.

Applicant points to the teachings at pages 13, 18, 19 and 33 of the specification which disclose the grain of the invention is made by crossing oil burdened protein laden corn plants with maize plants carrying the low phytic acid allele, the low phytic acid plant of the present invention can be developed by following the listed steps which do not take undue experimentation and can be done by one of ordinary skill in the art of plant breeding, the EMS mutagenesis technique to be employed, and a method of forming two inbreds which may be crossed to form a high yielding hybrid. Applicant additionally points out that a second method for obtaining the grain of the invention is set forth in the referenced international application WO92/08341. Applicant also points to the Declaration under 37 CFR 1.132 showing that methods for measuring oil and protein content were well known in the art as of the instant application's priority date, and the teachings of the specification at pages 15-17 indicating the prior development and public availability of high protein corn. Applicant further points to the specification as teaching the availability of plants carrying the low phytic acid allele as experimental material from the USDA, and to U.S. Patent No. 5,689,054, attached as exhibit A, as showing that the Neuffer EMS mutagenesis used by Applicant had been used to generate low phytic acid mutants before the priority date of the instant application. Applicant additionally points to the Declaration under 37 CFR 1.132 as showing that Applicant has made a large number of mutant inbred corn lines and hybrids falling within the scope of the present claims (reply pages 7-10).

As stated at pages 4-5 of the office action mailed February 7, 2002, and pages 5-6 of the office action mailed October 22, 2002, the Examiner maintains that it is well known in the art that EMS mutagenesis is nonspecific, and that the identity and number of genes altered by EMS treatment cannot be controlled or predicted. See for example Welsh (Fundamentals of Plant

Genetics and Breeding, 1981, John Wiley & Sons, NY) who teaches that chemical mutagens such as EMS randomly mutagenize the entire genome, simultaneously increasing the frequency of extraneous as well as desirable mutations (page 238 second full paragraph through page 240 third paragraph). Given that EMS mutagenesis is random and nonspecific, and given that the phenotype of the seed of different maize lines is differentially affected by their various genotypes, the disclosure of a single non-lethal mutant maize seed (UO95py) exhibiting the claimed phenotypic characteristics, combined with the disclosure of prior art methodology for mutagenesis and screening, does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which maize lines to mutagenize in order to obtain non-lethal mutant maize seed exhibiting the desired phenotypic characteristics. The undue experimentation lies in the selection of maize lines to mutagenize in order to obtain maize seed exhibiting the desired phenotypic characteristics, rather than in the application of screening techniques that would be within the abilities of one skilled in the art.

Additionally, given that various genotypes differentially affect the phenotype of the seed of different maize lines, the phenotypes of the offspring generated by crossing any oil burdened protein laden maize plant of any genotype with any maize plant of any genotype carrying the low phytic acid allele would be unpredictable, because the phenotypic effect of crossing two plants having different genotypes is unpredictable. See for example Welsh (Fundamentals of Plant Genetics and Breeding, 1981, John Wiley & Sons, NY) who teaches that the degree of heterosis observed in hybrid corn obtained by crossing inbred corn may vary from extreme to nonexistent (page 212 third full paragraph). Accordingly, the mere assertion in the specification that the grain of the instant invention can be made by crossing any oil burdened protein laden maize plant with

any maize plant carrying the low phytic acid allele is not sufficient to enable the claimed invention, because such an assertion does not provide sufficient guidance with respect to which oil burdened protein laden maize lines to cross with which maize lines carrying the low phytic acid allele in order to obtain maize seed exhibiting the desired phenotypic characteristics.

With respect to Applicant's assertion that the Declaration under 37 CFR 1.132 shows that Applicant has made a large number of mutant inbred corn lines and hybrids falling within the scope of the present claims, the Examiner notes that while the declaration asserts at page 5, #4, that Applicants have selected 20 inbred lines and produced 100 mutational events that were "stable, low in phytate and non-lethal", the declaration does not indicate the source(s) of the inbred lines, the relationship, if any, between them, or whether any of the inbred lines exhibit the claimed phenotypic characteristics. Absent specific reference to the genotype(s) and phenotype(s) of the 20 inbred lines, the relevance of declarant's assertion to the issue of enablement is unclear. The Examiner also notes that while the declaration asserts at page 5, #4, that by selectively crossing these inbred lines, Applicants have obtained more than 50 candidate hybrid combinations "which are low in phytic acid, high in oil, and high in protein", the declaration does not indicate which inbred lines were crossed or whether any of the more than 50 candidate hybrid combinations exhibit the claimed phenotypic characteristics. Absent specific reference to the genotype(s) and phenotype(s) of the 50 hybrid lines, the relevance of declarant's assertion to the issue of enablement is unclear. The Examiner additionally notes that while the declaration asserts at page 5, #5, that Applicants have made more than 50 non-lethal mutant maize hybrids that exhibit the claimed phenotypic characteristics, the declaration does not

reference to the genotype(s) of the more than 50 non-lethal mutant maize hybrids that exhibit the claimed phenotypic characteristics, the relevance of declarant's assertion to the issue of enablement is unclear. The Examiner finally notes that the analytical data representing the weight percent oil, weight percent protein and percent phytate reduction for grain from the hybrids set forth in Table 1 suggests that a limited number of parental lines appear to have been used to generate the hybrid plants that exhibit the claimed phenotypic characteristics. Given that a limited number of parental lines appear to have been used to generate the hybrid plants that exhibit the claimed phenotypic characteristics, and given that the phenotypic effect of crossing any two inbred lines to produce a hybrid is unpredictable, the specification does not enable claims to any maize seed of any genotype that exhibits the claimed phenotypic characteristics, as the specification does not provide sufficient guidance with respect to which inbred maize lines may or may not be crossed to produce a hybrid that exhibits the claimed phenotypic characteristics.

Remarks

No claim is allowed.

Claims 1-2, 17-18, 21, 23-24 and 28-30 are deemed free of the prior art due to the failure of the prior art to teach or suggest a non-lethal mutant maize seed having at least 5% by weight oil, at least 11% by weight protein, and at least a one third reduction in the phytic acid amount relative to wild-type maize seed, or a non-lethal mutant maize seed having at least 5% by weight oil, at least 13% by weight protein, and at least a one half reduction in the phytic acid amount relative to wild-type maize seed, or a non-lethal mutant maize seed having at least 6% by weight oil, at least 9% by weight protein, and at least a one half reduction in the phytic acid amount

relative to wild-type maize seed, or a non-lethal mutant maize seed having at least 5% by weight oil, at least 9% by weight protein, and at least a one third reduction in the phytic acid amount relative to wild-type maize seed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
July 23, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638